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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,902	01/18/2002	Wolfgang A. Renner	1700.0190004/BJD/SJE	7792
26111	7590	10/15/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/050,902

**Applicant(s)**

RENNER ET AL.

**Examiner**

Mary E. Mosher, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/21/04, 7/19/04.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 100, 135 and 176 is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/21/04</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-102,104,108,121-132,134-137,139-174,176-179,185-189 and 194-219.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12,36-42,50-85,87-99,157-172,194-197 and 199-218.

Continuation of Disposition of Claims: Claims objected to are 1-4, 6-11, 13-35, 43-49, 86, 100-102, 104, 108, 121-132, 134-138, 139- 156, 173, 174, 176-179, 185-189, 198, and 219.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 12, 36-42, 50-85, 87-99, 157-172, 194-197, and 199-218 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9/26/2003.

Claims 1-4, 6-11, 13-35, 43-49, 86, 100-102, 104, 108, 121-132, 134-138, 139-156, 173, 174, 176-179, 185-189, 198, and 219 have been examined to the extent that they read upon the elected species, except for examination of the generic and/or linking claims 1, 100, 135, and amended claim 176.

This application contains claims 12, 36-42, 50-85, 87-99, 157-172, 180-184, 194-197, and 199-218 drawn to an invention nonelected with traverse in Paper No. 9/26/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

Claims 1-4, 6-11, 13-35, 43-49, 86, 100-102, 104, 108, 121-132, 134-138, 139-156, 173, 174, 176-179, 185-189, 198, and 219 are objected to because they are not limited to the elected invention.

Applicant requests that the objection be held in abeyance pending the identification of allowable subject matter, at which time rejoinder of species linked by an allowable generic claim will be proper. However, the previous office action did identify generic allowable subject matter. Applicants have chosen to pursue claims broader than

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the indicated allowable genus, which necessitates continued rejection of the generic claims.

***Claim Rejections - 35 USC § 112***

Claims 1, 100, 135, and 176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 176, what is "6165" ?

Claims 1, 100, and 135 are rejected as indefinite for the same reasons as the previous rejection of claims 1 and 135. Applicant argues that the phrase "virus-like particle of a bacteriophage" is defined in the specification and that the claims are therefore definite. This argument would be convincing if the claims actually referred to "a virus-like particle of an RNA-bacteriophage." However, the claims recite "a virus-like particle comprising recombinant proteins, or fragments thereof, of an RNA-bacteriophage." Therefore it still is not clear if the intent is a particle resembling an RNA phage or more broadly any virus-like particle that comprises a fragment of an RNA phage (that is, contains at least two contiguous amino acids common to both the VLP and an RNA phage).

The rejection of claim 100 as indefinite for using the term "self antigen" is withdrawn in view of applicant's argument.

Claim 176 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition, does not reasonably provide enablement for a vaccine as claimed. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant argues that the invention is useful and clinical trials are not required. The examiner does not contest that applicant's products are therapeutically useful, merely that the evidence of record is insufficient to establish that phage-VEGFR2 immunogens are able to prevent disease according the conventional meaning of the term "vaccine." The examples showing protection from influenza challenge are not convincing, since this is not the subject matter elected for examination. This is a highly unpredictable art, and one skilled in the immunology art is unlikely to unquestioningly accept unsupported assertions regarding prevention of disease, even in the presence of data suggesting some beneficial immune response. This rejection could be obviated by amending the claim to recite immunogenic compositions rather than vaccines.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1 and 135 as anticipated by Mastico et al 5,698,424, is withdrawn in view of the amendment to the claims. The rejection of claim 100 as anticipated by Schiller et al US 2002/0081295 is withdrawn in view of the amendment to the claim.

***Claim Rejections - 35 USC § 103***

The rejection of claim 100 as obvious over the combined teachings of Chakerian et al and Renner is withdrawn in view of the amendment to the claim.

Generic claims 1, 100, 135 and 176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiller et al US 2002/0081295. These claims have been

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amended to exclude a sulfhydryl group at the core-end of the connection between core and antigen. Schiller teaches immunizing composition comprising virus-like particles presenting a repetitive array of self antigens. Schiller explicitly suggests using RNA phage virus-like particles, see paragraph 0054. Schiller also explicitly suggests using any chemically reactive species to link the core and the antigen, including several linkages that do not involve sulfhydryl groups, see for example paragraphs 59 and 60. Schiller further suggests compositions with adjuvants, see paragraph 0085. Therefore combination of a non-sulfhydryl linkage and an RNA phage virus-like core is prima facie obvious, absent unexpected results. Applicant states "As claims 103 and 121 were not rejected over Schiller et al, applicants presume that the Examiner has determined that these claims are allowable over this reference." This presumption is incorrect; as indicated in the previous Office action, search and examination was expanded from the elected species for generic and/or linking claims 1, 100, and 135; the other claims were examined to the extent that they read upon the elected species.

***Allowable Subject Matter***

The subject matter of claims 1-4, 6-11, 13-35, 43-49, 86, 100-102, 104, 108, 121-132, 134-138, 139-156, 173, 174, 176-179, 185-189, 198, and 219 would be allowable if limited to compounds, immunogenic compositions, and immunogenic methods involving a virus-like particle of an RNA-bacteriophage associated through a nonpeptide bond to VEGFR2 or an antigenic determinant thereof, where the particle presents VEGFR2 (or its determinant) in an ordered and repetitive array.

***Information Disclosure Statement***



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Applicant states that document AS95 could not be found, a courtesy copy of AS95 is enclosed, and requested indication of consideration on the record. This is an image file that now has 417 documents with the helpful identification "Nonpatent literature" or "foreign patent", and 8 IDS's each with multiple pages. The contents of image files are not searchable and there is no efficient way to figure out what "AS95" is supposed to be or which IDS it was originally listed on. What is this reference, what was the IDS filing date, and when did you file the copy? If it was listed on the IDS filed July 21, 2004, it has been considered.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

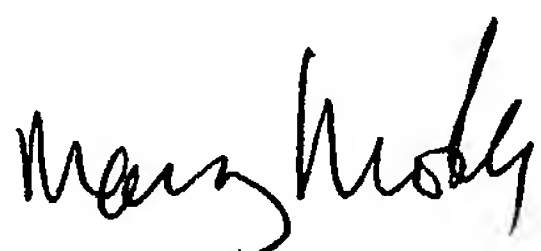


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/13/04

  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800 1600